



The regulation of cognitive enhancement devices: refining Maslen et al.'s model

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ABSTRACT

Our (2014) model for the regulation of cognitive enhancement devices (CEDs) received a great deal of interest from those involved in European device regulation and from academic commentators. Further, since the publication of our recommendations, the number of manufacturers of brain stimulation devices for non-medical purposes has increased, underscoring the need for a regulatory response. In this paper, we clarify aspects of our original proposal and address additional regulatory issues beyond our original focus on the sale of devices. We begin with theoretical points pertaining to the definition of a CED and the distinction between treatment and enhancement. We then respond to practical challenges raised by the prospect of implementing our regulatory framework. Next, we address some wider societal considerations relating to users and other stakeholders. Finally, we revisit the broader regulatory context within which the various discussions are situated.

KEYWORDS: cognitive enhancement devices, transcranial direct current stimulation, Medical Devices Directive, regulation, risk-benefit assessment, treatment-enhancement distinction

Our paper, *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*, was published in March 2014. In that paper, we argued that the sale of cognitive enhancement devices (CEDs)—such as transcranial direct current stimulators (tDCS) and transcranial magnetic stimulators (TMS)—should be regulated under medical devices legislation (for instance, the Medical Devices Directive (MDD) within the

European Union). We made further suggestions as to how such incorporation could be achieved and how devices should be assessed.

Following the publication of our paper, we received a great deal of interest in our proposals, both from those involved in European medical device regulation and from academic commentators. Furthermore, during this time, the number of manufacturers of brain stimulation devices for non-medical purposes has increased, underscoring the need for a regulatory response. In this present paper, we respond to suggestions and critique presented in five peer commentaries that appeared in the *Journal of Law and the Biosciences*. In providing this response, we hope to clarify aspects of our original proposal and comment on our current position regarding the regulatory change currently being effected at the European level. The commentaries were constructive, advancing debate and highlighting many additional regulatory issues beyond our original focus on the sale of devices. Since we do not have the space to reply at length to every point made in the commentaries, we select and discuss the more prominent points of disagreement, rather than celebrating the many points of agreement. We begin with the more theoretical points, moving through the practicalities of implementation, to wider societal considerations, finally revisiting the broader regulatory context within which the discussions are situated.

We first address conceptual points pertaining to the definition of CEDs and the distinction between treatment and enhancement, clarifying our view and isolating the features that have implications for the regulation of CEDs. We then turn to discussion of how consumers respond to and evaluate risk, underscoring the need for regulators to develop the framework against this background. We then reexamine what this framework should look like, responding to the related challenges from commentators that risk should be the sole consideration and that benefits of enhancement are difficult to measure. Next, we interrogate three societal concerns that extend beyond the structure and details of the regulatory framework: first, that our model does nothing to regulate the misuse of neither direct-to-consumer nor homemade devices, second, that prohibitive regulation might create barriers to reaping the net societal benefits that CEDs could offer and, third, that healthcare resources would be misused if CEDs were brought within medical devices legislation. Finally, we revisit the current European regulatory landscape to highlight the continued existence of a regulatory gap and the timeliness of the discussion of our proposals.

1. THEORETICAL ISSUES

1.1 Defining CEDs and distinguishing between treatment and enhancement

De Ridder, Vanneste, and Focquaert address concerns relating to the definition of a CED and the distinction between treatment and enhancement.¹ They raise a number of problems with the treatment-enhancement distinction and suggest that we need to ask ‘whether we are prepared to change the definition of health used by the Medical Devices Directive’. There are in fact three questions raised here. The first is whether our proposal requires a robust characterization of the treatment-enhancement distinction, the second is whether our suggestions, as we intended them, actually involve changing

¹ Dirk De Ridder, Sven Vanneste & Farah Focquaert, *Outstanding Questions Concerning The Regulation Of Cognitive Enhancement Devices*, 1 J. L. & BIOSCI. 316–21 (2014) (p. 317).

the definition of health implicit in the MDD (there is no explicit definition), and the third is whether the mere inclusion of CEDs within the MDD will have the de facto effect of changing the implicit regulatory concept of ‘health’ or ‘treatment’.

In response to the first question, we would maintain that it is in fact an advantage of our approach that it minimizes the importance given to the treatment-enhancement distinction and thus diminishes the need to characterize it in a way that is immune to criticism. On our approach, devices intended for enhancement are regulated in a similar manner to therapeutic medical devices. Thus, if some enhancement devices are misclassified as therapeutic devices, or vice versa, this will not have major implications for their regulation. What matters, from our perspective, are risks and benefits. By contrast, some alternative approaches, including the one recommended by De Ridder and collaborators, would regulate CEDs and therapeutic medical devices quite differently, with the result that misclassification would have more significant regulatory effects, since devices regulated under the General Product Safety Directive alone are held to less specific and less stringent standards. In short, we agree that the treatment-enhancement distinction is problematic—and some of us have elsewhere rejected it²—but we believe a desire to mitigate the problems it raises counts in favor of our approach, not against it.

We would also dispute the suggestion that our approach requires any modification to the concept of health. Our proposal was not to ‘change the definition of health’ (nor ‘treatment’) but, rather, to bring some non-therapeutic devices, which do not aim to improve health problems, within the remit of the MDD. Our proposals involved leaving the definition of a medical device used by the MDD unaltered. CEDs would not be medical devices on the MDD definition. Instead, an ancillary positive list is proposed to bring specific devices with a *non-medical* purpose within the remit of the MDD *alongside* those devices defined as medical devices according to the criteria employed in the Directive. By proposing an ancillary list for specific cognition-affecting devices without a medical purpose, we in fact *reinforce* the concepts (ie medical and non-medical) underpinning the European Commission’s proposed creation of Annex XV for implantable and other invasive devices for which the manufacturer claims only a non-medical purpose.³ We proposed that this list should be extended to include non-invasive neuromodulation for non-medical purposes.

However, the third implicit question indeed requires consideration: Will there be a de facto change in what is meant by ‘health’ and ‘treatment’ if CEDs are regulated under the MDD? Arguably, the mere association of CEDs with therapeutic medical devices could result in an expansion of the concepts of treatment and health. This is, of course, an empirical question. The possible implications of a shift in what is seen as ‘health-related’ or ‘therapeutic’ are addressed later in De Ridder, Vanneste, and Focquaert’s commentary. There, they suggest that medical device regulation might underscore the ‘illusion’ that devices are beneficial. This is indeed an important concern. However, we suggest that the idea that tDCS and TMS techniques can yield cognitive enhancement

² See Julian Savulescu, *Genetic Interventions and the Ethics of Enhancement of Human Beings* 516–35 (Bonnie Steinbock ed., 2007); M. Dunlop & J. Savulescu, *Distributive Justice and Cognitive Enhancement in Lower, Normal Intelligence*, 32 MONASH BIOETHICS REV. 189–204 (2014).

³ See at 116, http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf (last accessed May 28, 2015).

in healthy adults is not a mere illusion.⁴ Further, we suggested that regulatory approval of moderately risky brain stimulation devices should be dependent on evidence of at least *some* degree of ‘performance’.⁵ In this respect, it would be important to notify consumers explicitly on which population the CED has shown to be beneficial while reminding that it can be ineffective or detrimental to other populations.⁶ Regulation would therefore go some way towards ensuring that effects are not illusory for those devices that are approved (although individuals could believe effects to be bigger than they are). Whilst we concede De Ridder, Vanneste, and Focquaert’s point that there is currently ‘no substantive evidence that CEDs produce lasting effects outside of research and clinical settings’ (p. 320), there is a wealth of scientific research that provides proof of concept for the cognitive enhancing effects of tDCS and TMS techniques. That the CEDs on the market have not been subject to objective assessment is part of the reason why regulation is needed and counts in its favor.

Kuersten and Hamilton also raise concerns about our definition and characterization of CEDs.⁷ They argue that contemporary scholarship shows no serious harms associated with the use of neurofeedback or tDCS. In response to this, we wish to point out—particularly in relation to active devices used for tDCS and TMS—that, whilst devices have indeed been used safely in the laboratory, and the regulated devices that researchers use in such contexts are indeed conducive to safe use, these facts do nothing to ensure that the unregulated devices on sale for enhancement exhibit the same safety profile. First, the exclusion criteria for brain stimulation research are much more conservative than marketed exclusion criteria. Second, while brain stimulation experiments last usually between a single session to a dozen (the latter is a relatively rare scenario), there is not safety data on the usage of brain stimulation over a long period of time such as months or years. Essentially, regulation is needed to ensure that devices sold for enhancement are as similar as possible to those devices about which Kuersten and Hamilton make their safety claims.

Indeed—and to illustrate the point from another perspective—Fitz and Reiner raised concerns about the foc.us device in their commentary:

the internal electrodes exceed the general safety guidelines for current density at all stimulation levels, the voltage limits do not behave as specified in the manual, the device behaves unpredictably when its connection to the head is lost, and under some circumstances the foc.us can generate small voltage current spikes.⁸

Accordingly, we emphasize: just because tDCS can be safe does not mean that all of the particular devices on sale are meeting the same level of safety.

⁴ Roi Cohen Kadosh, *Using Transcranial Electrical Stimulation to Enhance Cognitive Functions in the Typical and Atypical Brain*, 4 *TRANSL. NEUROSCI.* 20–33 (2013); Eran Dayan et al., *Noninvasive Brain Stimulation: From Physiology to Network Dynamics and Back*, 16 *NAT. NEUROSCI.* 838–44 (2013).

⁵ Performance is the medical devices analog of ‘effectiveness’.

⁶ Amar Sarkar, Ann Dowker & Roi Cohen Kadosh, *Cognitive Enhancement or Cognitive Cost: Trait-Specific Outcomes of Brain Stimulation in the Case of Mathematics Anxiety*, 34 *J. NEUROSCI.* 16605–10 (2014).

⁷ Andreas Kuersten & Roy Hamilton, *the Brain, Cognitive Enhancement Devices, and European Regulation*, 1 *J. L. & BIOSCI.* 340–47 (2014) (p. 325).

⁸ Nicholas S. Fitz & Peter B. Reiner, *Buttressing Regulation of Cognitive Enhancement Devices With Principles Of Harm Reductio*, 1 *J. L. & BIOSCI.* 322–27 (2014).

Further, at the end of their commentary, and perhaps in tension with their assertion that the sorts of CEDs we discuss present no significant risks, Kuersten and Hamilton say that low-risk devices should *not* be excluded from on-going oversight, since ‘so much concerning the brain, what affects it, and how remains unknown’ (p. 347). We wish here to emphasize that low-risk devices, as we envisioned them, would typically be non-active devices such as neurofeedback equipment, which they correctly claim pose no risks *qua* devices (see below). Given their comments on the safety of neurofeedback, especially considered simply as a device, we would be surprised if they would think that such equipment required on-going oversight. Thus, even if there is room to disagree about whether CED is the right label for non-active devices (as we discuss below), we in fact seem to agree on the lack of need for the continual regulation of low-risk devices, such as those that do not transfer energy through the skull.

Kuersten and Hamilton object to our inclusion of neurofeedback as a CED. We concede that neurofeedback equipment might not constitute an archetypal enhancement device. However, in offering our definition of CEDs, we were not aiming to provide the definitive view on what does and what does not fall within this category. Our interest in offering a definition was only to facilitate identification of a class of non-therapeutic devices that should receive regulatory attention and, on that definition, neurofeedback plausibly does qualify as a CED.

Note also that doubts about whether neurofeedback equipment qualifies as a CED on a precise understanding of that term could also be raised regarding tDCS equipment, which Kuersten and Hamilton believe does qualify. They argue that ‘what actually affects the brain is therapy used with [neurofeedback equipment]’ (p. 341). But tDCS also only enhances cognitive performance when combined with cognitive training exercises, so could be excluded from the category of CEDs on similar grounds.⁹

Nevertheless, Kuersten and Hamilton are right to highlight that tDCS directly modulates brain activity whereas neurofeedback modulates it through psychological mechanisms. We have no problem with the suggestion that this is a significant difference, and indeed it informs our suggestion that tDCS and TMS should be classed as IIa or IIb devices, due to their active nature, and neurofeedback should be in class I, if regulated at all.

Kuersten and Hamilton next argue that including CEDs under the definition of a medical device would not result in our suggested problem of overbreadth (which we suggested would occur if the definition of a medical device were to be altered), since devices, they claim, would be limited by the definition to those that ‘investigate, replace or modify the anatomy or a physiological process’. Their claim is based on the assumption that CEDs could fall under the definition as it is currently articulated.

However, it was the possibility that an *altered* definition would be overbroad that we thought counted in favor of a supplementary positive list. In setting out our proposals, we worked on the assumption that the current definition *did not in fact* capture CEDs (due to the principal criterion that a medical device be intended to treat, prevent or diagnose) and that changing the definition to remove this principal criterion across the board *would have the result* that it would then be overbroad. If the principal criterion

⁹ Roi Cohen Kadosh, *Modulating and Enhancing Cognition Using Brain Stimulation: Science and Fiction*, 27 J. COGN. PSYCHOL. 141–63 (2015); Marinella Cappelletti et al., *Transfer of Cognitive Training across Magnitude Dimensions Achieved with Concurrent Brain Stimulation of the Parietal Lobe*, 33 J. NEUROSCI. 14899–907 (2013).

were simply that a medical device investigate, replace or modify the anatomy or a physiological process then all sorts of devices would fall under the remit of the MDD—from earrings to nail extensions. Indeed, the European Commission used precisely this argument to support the creation of a positive list of implantable or other invasive devices without a medical purpose.¹⁰ According to their *Impact Assessment On The Revision Of The Regulatory Framework For Medical Devices*, the definition of a medical device stipulates that it be intended for treatment, prevention or diagnosis, and the removal of this criterion would result in overbreadth, making a positive list the preferred solution in the case of certain cosmetic devices.¹¹ Our argument for an analogous list for CEDs is based on the assumption that the European Commission is correct in its understanding of the MDD and the implications of the current and possible definitions employed therein.

2. PRACTICALITIES AND STRUCTURE OF THE REGULATORY FRAMEWORK

2.1 Consumer approach to risk

Fitz and Reiner broadly support our proposals and endorse our central claim, viz. that the regulatory framework for medical devices should be extended to include CEDs.¹² Nevertheless, they raise a concern about the ability of CED users to evaluate the risks of CEDs, saying that ‘evidence that consumers are in a strong position to evaluate the risks associated with CED use is lacking’ (p. 323).

Whilst we agree that consumers will not be perfect rational calculators, we emphasize that our proposals would eliminate devices from the market that were manifestly dangerous or far more dangerous than needed to serve their intended function. In addition, our liberal view is committed to the contention that allowing some room for error in consumers’ weighing of benefits vs. risks in relation to their individual well-being can be a justifiable cost of allowing individuals greater autonomy and freedom of action. We stress also that what the risks of devices are—their nature and likelihood—is something that would, in line with the procedure for medical devices, be assessed by a group of experts prior to approval for the market. This information would have to be disclosed on product labeling and instructions.

So, although we agree that leaving some room for consumer valuation of risk leaves open the possibility that individuals will not factor this carefully into their decision whether to use a product, we contend that this is an acceptable cost of a liberal approach to regulation. Further, we would like to emphasize that the current lack of regulation implicitly signals to home users that there are no real concerns with CEDs, as otherwise they would have been regulated—ie the perception is likely to be that, given the lack of regulation, there are no risks for consumers to evaluate at all. Thus, even if consumers are not perfect risk calculators, the current situation is likely to be more misleading than one in which risks have been identified by regulators.

¹⁰ http://ec.europa.eu/health/medical-devices/files/revision_docs/revision_ia_part2_annex1_en.pdf (last accessed May 28, 2015).

¹¹ *Id.* at 11.

¹² Fitz & Reiner, *supra* note at, 322, 327.

King, Gavaghan, and McMillan provide an interesting critique of our proposals relating to consumer assessment of CEDs, and in particular their risks and benefits.¹³ They agree that the concept of medical benefit is not always appropriate for CEDs (especially where designed and sold *only* for enhancement) and that well-being would be the theoretically appropriate construct when assessing such CEDs. However, they suggest that well-being, harm and risk are difficult to assess in the pre-market approval process and raise a particular concern about the phenomenon of ‘risk compensation’. The central feature of this phenomenon is that some individuals have a propensity for taking a certain level of risk and will increase the riskiness of what they are doing until this propensity is met. They therefore challenge the assumption that pre-market approval will make the use of CEDs safer overall, especially in the context of experimental home use. They suggest that, where users are determined to use devices in a risky way, they will do so despite safety standards.

In response to this, we raise a point of empirical uncertainty, and emphasize what can still be achieved through regulation, despite the phenomenon of risk compensation instantiated in some individuals. It might be true that people will tend to fulfill their propensity for a particular total amount of risk in their lives, but it is unclear whether they do this by assuming superfluous risk to achieve a particular goal or seeking further risky goals. Perhaps, as King and colleagues suggest, achieving one goal more safely allows one to assume additional risk in relation to other pursuits. However, a risk quota might also be met by increasing or maintaining the level of risk one exposes oneself to in pursuit of one’s current primary goal. Which is the case is likely to depend on the number of goals one believes to be valuable to pursue. If CEDs are made safer, would users with high risk thresholds seek to obtain riskier devices, or would their risk quota be freed up to pursue additional risky activities?

The question is essentially whether individuals tend to increase riskiness *across all activities* until their risk propensity is met, or whether they increase the riskiness *of every activity* to some threshold level for each activity, regardless of how superfluous this risk may be. If the former, risk reducing regulation could still have benefits in the form of facilitating pursuit of other risky, but perhaps all-things-considered valuable, activities.

Even if individuals with a high risk threshold are inclined to practice riskier use as the device itself becomes safer, we assume that King and colleagues would agree that it is still better that the devices available pose as low a risk as possible to achieve their effects, and that unjustifiably dangerous devices are prohibited from placement on the market. Requirements for safe design could, to some extent, further promote safe use—eg by using failsafe mechanisms, audible warnings, and limits on stimulation duration and strength. An individual’s propensity to take risks with a product does not render consideration of that product’s safety redundant. By analogy, just because some individuals routinely drive dangerously, this does not negate the need to try to make cars as safe as possible. It is also important to emphasize (as King et al. indeed acknowledge) that not all individuals engage in risk compensation. Even if those engaging in risk compensation reap no overall benefit from making CEDs safer, failing to minimize risks would unfairly jeopardize those who do not so compensate.

¹³ Mike King, Colin Gavaghan & John McMillan, *Medical Regulation Of Cognitive Enhancement Devices: Some Concerns*, 1 J. L. & BIOSCI. 334–39 (2014).

2.2 Regulatory focus on risk and the difficulty of measuring enhancement ‘benefits’

Johnson, Gillett, and Snelling suggest that the most convincing argument in favor of our position is based on the regulatory assessment of risk, which they believe should be the sole consideration in pre-market assessment.¹⁴ We suggest here that our respective proposals are not as different as they may have seemed, as we proposed that risk should be the primary regulatory concern. However, we diverge from the position advocated by them in our contention that objective improvements to cognitive capacities are amenable and relevant to assessment.

Johnson, Gillett, and Snelling propose that regulators should define the ‘baseline’ (or, we infer, ‘upper limit’) level of risk that society feels an individual should be able to take (eg skydiving or climbing), and then require manufacturers to quantify risks only. They argue for this position by pointing out that when technologies are new, and particularly when new technologies are used for an innovative application, variation in the effects on individuals and useful endpoints may not be obvious *ab initio*. Our first response is to note that the same applies for risks—novel applications may present novel and variable risks that are as difficult to predict as the cognitive improvements one might obtain from such applications. Our second response is to emphasize that the model we proposed is actually quite close to a risk-only model; at least, it is a risk-first model. We suggested using risk as the primary way of categorizing a device and that benefits should only be considered in terms of objective improvements—eg demonstrated improvements in a cognitive capacity, such working memory—which are precisely the sorts of effects about which manufacturers make their claims.

Importantly, this consideration of objective benefit is not intended to downplay the broader benefits that an individual might attain from using a device. Whilst objective benefits can be considered, they must not be thought to constitute the only determinants of well-being. Nonetheless, regulators should still ensure that consumers are provided with information on objective benefits. Indeed, the distinction between ‘thick’ and ‘thin’ considerations of well-being drawn by King, Gavaghan, and McMillan is illuminating in this regard. Thin well-being, they say, consists only in ‘all-purpose goods’, whereas a thick well-being incorporates the individual agent’s conception of value and his particular circumstances. This applies to effects in both directions. An objective impairment in, say, verbal working memory (that occurs as a trade-off of an objective improvement in, say, visuospatial working memory), will present the very same challenges for quantification, despite such impairment constituting a risk rather than a benefit. To the extent, as the risk only model assumes, that objective risks can be quantified (and impairment in verbal working memory indeed permits such quantification) objective benefits along the same sorts of dimensions can also be quantified).

Further, we suggested that room should be made to account for the difficulty of measuring effects (positive or negative) on thick well-being. Our proposal was that, once the manufacturer had made it clear what the objective benefits and risks are for moderately risky devices, the consumer should have the freedom to decide whether that benefit–risk ratio is acceptable for them (for example, because they expect it to result in a net gain in thick well-being). On the other hand, we proposed that high-risk devices, presenting risks that might be classed ‘all-purpose bads’ (eg a high risk of seizure), should

¹⁴ Reuben Johnson, Grant Gillett & Jeanne Snelling, *Regulation of Cognitive Enhancement Devices: Commentary*, 1 J. L. & BIOSCI. 328–33 (2014).

be prohibited for sale on the consumer market. Whatever the individual's life plans, in the preponderance of cases of healthy adult use, a seizure is unlikely to promote these plans.¹⁵ Where there is scope for disagreement about the value of an effect—for example as to whether a small impairment in verbal working memory is a reasonable price to pay for a similarly sized improvement in visuospatial working memory—regulation should err on the side of allowing consumer freedom. Level of acceptable risk therefore plays a greater role than quantification of benefits in our overall framework.

As an objection to our model, King, Gavaghan, and McMillan present the example of the surgical insertion of a ventriculoperitoneal shunt to treat normal pressure hydrocephalus. They note that this would be a high-risk procedure on our proposals, as it comes with the risk of seizures, stroke, paralysis, and death. Moreover, there has never been a comprehensive multicenter randomized controlled trial to demonstrate the performance of this product. This is thus a high-risk procedure for which there is no good evidence of benefit. Nevertheless, they seem to suggest, the use of this procedure should be permitted. It might seem, then, that consistency requires permitting the use of some high-risk CEDs as well, calling into doubt our claim that high-risk CEDs should not be allowed on the market.

In response, we would note that patients with normal pressure hydrocephalus typically have much more to lose from non-intervention than do healthy individuals considering whether to employ CEDs. Indeed, one might think that advancing dementia is amongst the worst fates that might befall a person. There is thus a case for tolerating much greater risk in devices intended to treat this condition than in CEDs.

King and collaborators also use the ventriculoperitoneal shunt example to suggest that it may not be practical to enforce the provision of evidence-based measures of efficacy to consumers for CEDs. In response to this, we emphasize that we do not have in mind a requirement such that each manufacturer must perform a randomized controlled trial using their device. Research investigating tDCS and TMS in healthy adults is demonstrating efficacy, and we envisage that manufacturers should be required to show how their device complies with design parameters equivalent to those that have been shown in the scientific literature to produce enhancement effects. For example, devices with electrodes positioned in locations on the scalp that have no evidence of producing the particular effect claimed by the manufacturer should not be approved for sale alongside such claims.¹⁶ Manufacturers must be able to identify a credible body of scientific literature that supports the claimed efficacy and safety, given the product's characteristics—electrode location, stimulation intensity, duration, and so on. Further, we agree with King, Gavaghan, and McMillan that manufacturers should be required to

¹⁵ The possibility that a seizure might provide some benefit is conceivable in only very particular cases of mental disorder, wherein the prescription and oversight of the intervention would strictly be confined to treatment in the medical context. For example, trials have shown the efficacy of magnetic seizure therapy for treatment-resistant depression (See for example, Sarah Kayser et al., *Magnetic Seizure Therapy In Treatment-Resistant Depression: Clinical, Neuropsychological And Metabolic Effects*, 45PSYCHOL. MED. 1–20 (2014)). However, the inducement of seizures is not a purpose appropriate for an over-the-counter CED that is used as a CED. In the context of healthy adults, such an effect will likely constitute an 'all-purpose bad', in the sense that implies the opposite of an 'all-purpose good'.

¹⁶ For example, the first model of the foc.us device used a montage not proven to achieve the effects on focus that the manufacturers claimed.

state clearly the lack of evidence for any unsubstantiated claims, if they are to be allowed to make them at all.

Kuersten and Hamilton also comment on the risk–benefit assessment of CEDs, and the standard to which we proposed they should be subjected. They argue that there is a lot of room for maneuver in the MDD to assess ‘acceptable risks when weighed against the benefits’ (p. 346). This is true, but we nonetheless think a framework for assessment is helpful, especially when the devices in question purport to offer ‘non-medical’ benefits, a concept for which medical device regulators have little precedent. Indeed, we argued against adopting the approach originally suggested by the MHRA for cosmetic devices, which is very risk-averse: according to their approach such devices must present ‘no or the minimum acceptable risk’, as they confer no ‘clinical benefit’.¹⁷

Conceding that some framework could be helpful, Kuersten and Hamilton suggest that, because the concept of benefit is ‘nebulous’, in the case of CEDs, only risk should matter for pre-market approval. In fact, as discussed above, we are broadly in agreement with such a position—benefits become increasingly harder to quantify and assess as they move beyond the sorts of benefits that enable individuals to pursue the standard range of activities most people wish to pursue. For example, not being in great pain would count as a benefit for most people, regardless of what they valued, but a small improvement to mathematical ability, for example, would not permit such evaluative consensus. As noted above, our inclusion of regulatory consideration of benefits for moderately risky devices was intended only to refer to objective improvements—about which consumers should not be misled. For example, if manufacturers claim that their device improves, say, the user’s linguistic fluency, this is a claim that can be tested and measured objectively. How ‘beneficial’ such an objective improvement is to any particular person will vary depending on their goals, but there will be a fact of the matter about whether the device is able to confer such an improvement aside from the subjective question of how valuable this improvement might be. Certainly, we would advocate regulating the claims that manufacturers make in relation to what their devices can achieve. However, far from our proposals being ‘overly paternalistic’, we argued that where there was room for disagreement about how to quantify a benefit in relation to risks, regulation should err on the side of consumer freedom.

3. WIDER SOCIETAL CONSIDERATIONS

3.1 Do-it-yourself tDCS and misuse of devices

Further to their concerns regarding individuals’ abilities to weigh risks, Fitz and Reiner emphasize the remaining problem of ‘do-it-yourself’ (DIY) users who, in constructing devices from scratch, will be afforded no protection by the regulation of direct-to-consumer devices. One of their proposals, with which we agree, is to bolster our recommendations with additional attempts at ‘active harm reduction’.¹⁸ They suggest

¹⁷ MHRA, *The Revision Of European Legislation on Medical Devices*, Nov. 2012, <http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con205362.pdf> (last accessed May 28, 2015), 10.

¹⁸ This proposal was discussed and endorsed by some of us in our respective talks at the Institute of Medicine’s ‘Non-Invasive Neuromodulation of the Central Nervous System’ workshop (Mar. 2–3, 2015, Washington DC); Hannah Maslen, ‘Neuromodulation and Unsupervised Use’; Roi Cohen Kadosh, ‘Non-Medical and Investigational Uses’.

that members of the professional community could join together to create an ‘inclusive online community’, where information could be gathered and disseminated with professional oversight. We are broadly sympathetic with much of what they propose and would support the creation of an inclusive online community, were there to be sufficient expert interest in creating and maintaining it. Indeed, we are currently exploring how expert advice could be dispensed via existing fora, such as Reddit.¹⁹

De Ridder, Vanneste, and Focquaert also raise the problem of unsupervised use and suggest potential solutions in the form of age limits, safety-by-design, and requiring user licenses. We agree that the unsupervised use of CEDs needs consideration, but do not agree that this should lead to their apparent conclusion that we should regulate the use of CEDs *rather than* their placement on the market. The first task must be to ensure that the devices that people use (unsupervised or otherwise) are not unnecessarily dangerous or simply defective by design. This can be achieved for example through European medical device law, which focuses on premarket requirements and reporting on post-market experience, even though it does not regulate use (apart from requirements related to the instructions the manufacturers must provide). There is no point carefully regulating use if the devices being used are not safe to begin with. Further, the authors’ suggestion that CEDs should be made safe by design requires enforcement beyond that granted by the General Product Safety Directive, and this is precisely the sort of thing that could be achieved by a model of the sort we propose.

3.2 Prohibitory effects of regulation and barriers to societal benefits

De Ridder, Vanneste, and Focquaert raise the concern that the societal benefits of enhancement might be lost if devices are in fact effective but regulated. In relation to this, we emphasize that the regulation we advocate is not akin to prohibition. To the extent that our proposals would prevent devices from being placed on the market, this would be limited to very dangerous devices or devices making implausible claims—hardly the sorts of devices that would confer net societal benefits. The important point that many other commentators on our model appear to overlook is that the effectiveness of brain stimulation techniques as a *type of intervention* does not guarantee the effectiveness of *particular token devices* claiming to be of this effective type. Regulation would assess devices at this case-by-case level.

Moreover, as low risk, effective devices are developed, these would be available under our proposal and a vigorous market will emerge. This would compete with the ‘black market’ of DIY and present consumers with a range of choices.

3.3 Misuse of public resources and the role of healthcare

De Ridder, Vanneste, and Focquaert raise concerns about the misuse of resources, which assumes a position markedly different from that which we set out in our paper. They argue, persuasively, that resources should be directed to the most important causes and that enhancements might not be of a high enough priority to warrant use of our limited resources. We agree that limited resources need to be allocated carefully, but our proposal does not threaten such allocation: the devices that would be prohibited under our proposal are ones that would certainly not warrant significant investment of public resources, and our proposal leaves open how resources should be allocated

¹⁹ See <http://www.reddit.com/r/tDCS> (last accessed May 28, 2015).

among those that would be permitted. Perhaps De Ridder and collaborators assumed us to be advocating the inclusion of CEDs under the healthcare funding arrangements, but this is not what we envisaged. The extension to the scope of the MDD, as we recommend it, has no direct implications for the distribution of healthcare resources. Relatedly, the authors ask whether the regulation of CEDs requires new regulations regarding who can use them. Again, the answer is for the most part no: our proposals merely affect what can be placed on the market for consumers to purchase. The only exception should be restrictions governing the use of CEDs on children or vulnerable adults through contraindication labeling and the criminal law. In contrast, adult consumers will not need a prescription to purchase and use CEDs on themselves. Indeed, King, Gavaghan, and McMillan provide a compelling argument in their commentary for why medical practitioners should not serve as gatekeepers to cognitive enhancement.

Also of relevance to the question of the correct place of enhancement in healthcare, King, Gavaghan, and McMillan suggest that our reference to formally trained practitioners was not developed. We used this phrase in relation to the use of CEDs in children and vulnerable adults, since our proposals envisaged that healthy adults would be able to directly purchase and use CEDs, with no medical intermediary. They ask whether we envisage a further tier of regulation and raise a number of interesting points that would need to be addressed if medical professionals or those offering alternative therapies were to serve as gatekeepers to the use of CEDs in such populations. They are correct that the regulation of such practice would indeed introduce a 'further tier of regulation', and we acknowledge that this issue was not addressed in our original paper. However, we believe that the scope for the permissible use of CEDs on children may be limited. Further, neuromodulation offered to vulnerable adults overseen by medical professionals will primarily be governed by existing medical ethical guidelines, since such use is likely to be therapeutic and hence occurs within the clinical domain.

In relation to children, some of us have recently argued that brain stimulation for 'enhancement' should not be permitted until roughly the age of 16.²⁰ King, Gavaghan, and McMillan are correct that further thought is needed to establish how use in adolescents should be controlled, and with whose oversight. However, ensuring the safety of devices that might be used for enhancement in children and placing controls on such use are separate issues and both are important. Whilst our proposals were concerned with controlling which devices are sold directly to consumers, we agree that the regulation of services, especially those offered to children needs close attention.

4. THE CURRENT EUROPEAN REGULATORY CONTEXT

4.1 The root and extent of the regulatory gap

Kuersten and Hamilton object that we fail to cite much law on the remit of the MDD. The suggestion seems to be that this has left us underinformed. Attempting to clarify the current regulatory situation, they say that instead of the definition of a medical device being the significant factor in the non-application of the MDD to CEDs, CEDs are instead unlikely to fall under the MDD because 'manufacturers targeting the general market are discouraged from intending them "for a medical purpose"' (which they

²⁰ Hannah Maslen et al., *Brain Stimulation for Treatment and Enhancement in Children: An Ethical Analysis*, 8 FRONT. HUM. NEUROSCI. 953 (2014).

argue manufacturers have ‘considerable latitude’ to do) (p. 344). Manufacturers are deterred, they say, because intending that a device be used for a medical purpose mandates costlier and more time-consuming requirements. We suggest that this is precisely the problem: manufacturers should not be able to evade regulation just because they deem it to be too burdensome. We are fully aware that it is the manufacturers’ intentions—identifiable from the claims they make in relation to their products—that are instrumental in bringing a device within the definition of a medical device. We argue that, particularly in the case of brain stimulation devices, opting not to fall under the definition of a medical device should not be a possibility.

However, Kuersten and Hamilton suggest that manufacturers’ intentions will in fact not matter once a new definition comes in to force, which will ‘specifically define a medical purpose’. They cite the MHRA’s overview of the current proposals for the current revision of medical devices legislation, proposals with which we are very familiar. They quote the document as follows, saying that the definition of medical purpose will ‘remove this decision from manufacturers’:

‘[M]edical device’ means any instrument, apparatus, appliance, software, implant, reagent or other article, intended by the manufacturer to be used alone or in combination, for human beings for one or more of the specific medical purposes of... investigation, replacement or modification of the anatomy or of a physiological process or state (pp. 343–4).

From this quotation, we suggest that it cannot be seen how the manufacturer’s intentions become irrelevant; on the contrary, they are referred to explicitly. Further, rather than the indents *defining* medical purpose, the scope of medical purpose is *constrained* to the specific instances given in the indents. Indeed, the consultation documents from the European Commission and the UK’s Medical and Healthcare Products Agency underscore the continued relevance of the medical/non-medical purpose distinction in relation to devices that replace or modify anatomy: their proposal of a positive list (in Annex XV) of implantable or other invasive devices without a medical purpose would be redundant if *any* replacement or modification of anatomy were to constitute a medical purpose.²¹ Again, the indents in the definition of a medical device serve to constrain, rather than define, medical purpose. Thus, we rely not only on the Court of Justice decision, but also on the interpretation of the MDD offered by the MHRA and other European Commission documents. Kuersten and Hamilton perhaps think that there should not be a gap, or may think that the definitions should be interpreted differently. But the fact is, given the way the definitions are currently being understood by the relevant parties, it will take more than the cited revised definition of a medical device to bring CEDs within the scope of the MDD.

²¹ For further details and justification of Annex XV from the European Commission and MHRA; see at 29, 116, 171, http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf (last accessed May 28, 2015); see at 10, <http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con205362.pdf> (last accessed May 28, 2015); see at 7, 8, <http://www.ipem.ac.uk/Portals/0/Documents/Consultations/Revision%20of%20European%20Legislation%20on%20Medical%20devices%20All%20responses%20April%202013.pdf> (last accessed May 28, 2015).

5. CONCLUSION

We were gratified that our paper prompted so much discussion. In reading the commentaries and articulating our responses, it became apparent that the comments and critiques served foremost to highlight the modest scope of our original proposals. Whilst we still believe that pre-market approval is highly important for CEDs—especially for those that transfer energy across the skull—there are many other regulatory challenges that remain unaddressed. In particular, the challenge of promoting safe use is not to be underestimated. The further proposals made in these commentaries serve to set an agenda for continued discussion of the optimum integrated policy response to CEDs and, indeed, other new and emerging technologies designed for enhancement.

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